September 1, 2020

United Healthcare
Medical Policy Department
9500 Bren Road East
Minnetonka, MN 55343

via Email: mpq@uhc.com

Re: Epiduroscopy, Epidural Lysis of Adhesions and Discography, Policy Number 2020T0206S

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to comment on your policy *Epiduroscopy, Epidural Lysis of Adhesions and Discography, Policy Number 2020T0206S.*

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

While we agree with the classification of other procedures as unproven or not medically necessary, we do not agree with this classification for provocative discography. Provocative discography is well-established and has a strong extant evidence base. It is an important tool to assist in the diagnosis of chronic low back pain refractory to conservative treatment. Appropriate coverage criteria and a thorough description of the supporting evidence are outlined in the North American Spine Society's *Coverage Policy Recommendations on Discography* (attached).

The undersigned societies appreciate the opportunity to provide these comments and would welcome the opportunity to work with United Healthcare to establish a reasonable coverage policy that will eliminate inappropriate utilization while preserving access to provocative discography for appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Physical Medicine and Rehabilitation

American Society of Anesthesiologists

American Society of Neuroradiology

American Society of Spine Radiology

North American Neuromodulation Society

North American Spine Society

Society of Interventional Radiology

Spine Intervention Society

Attachment:
North American Spine Society. Coverage Policy Recommendations: Discography. 2019.

Discography

NASS
NORTH AMERICAN SPINE SOCIETY

DEFINING APPROPRIATE COVERAGE POSITIONS

Endorsed by:

SPINE INTERVENTION SOCIETY
SIS

COVERAGE COMMITTEE

NASS Coverage Policy Recommendations

NASS Coverage Committee

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Coverage Policy Recommendations

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ISBN 1-929988-59-1

Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 9/26/16; information and data available after 9/26/16 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Background Information

Chronic low back and neck pain have been a significant problem in the population that continues to increase the overall cost of the health care delivery system. The diagnosis of discogenic pain in both the cervical and lumbar spine can be difficult since patients often present with or without radicular symptoms. Recently, diagnosis and subsequent treatment have been advanced with newer imaging studies, and MRI has proven to be extremely useful in defining the disc pathoanatomy. Discography is often used to distinguish a painful from a non-painful intervertebral disc. Combining positive MRI imaging with provocation discography has led to treatment opportunities for many patients.[1-4]

Unfortunately, the degenerative appearance of the disc and the presence of annular fissuring often do not correlate with pain generation. In the lumbar spine discogenic pain was found in 22% of the patients presenting with chronic low back pain.[5] This leads to the inevitable dilemma of diagnosing painful degenerative discs from non-painful degenerative discs. Discography has been used to correlate MRI degenerative findings with pain experienced by the patient.[1-2] The paucity of prospective studies in the literature further compounds the issue. The lack of an adequate control for comparison has made it even more difficult.[6-7] As was pointed out in one review, one of the hallmarks of a positive discogram is concordant pain provocation, which is not possible in people without low back pain.[8-10] Others have hypothesized that surgical outcomes should be the "gold standard" by which to judge the relevance of discography.[11-14] Also, the presence or absence of fusion was not evaluated.[9] When taking into account the presence of a solid arthrodesis, false positive scores decrease.[3-4]

With the introduction of manometric pressure measurements and subsequent reanalysis, the false positive rate for lumbar discography was markedly reduced.[10, 15-16]

In 1995, NASS developed a position statement on lumbar discography.[17] This was updated after a comprehensive review in 2003.[18] There were no major changes at that time. Based on the United States Preventive Services Task Force criteria, the indicated evidence has been determined to be level 2 for lumbar discography.[6] The incidence of discogenic pain was found to be 26% and false positive rates with discography were 9.3%.[6] Research indicates that the false positive rate for lumbar discography should be 0 to 10% when performed using small volumes (<3.0 cc) and pressures <50 PSI.[15]

Scope and Clinical Indications

Lumbar and Cervical Disc Stimulation (Provocation Discography) are indicated when all of the following criteria are met:

1. The presence of pain and some functional disability for a period of at least 6 months despite conservative therapy. This pain needs to be in a location that could reasonably be caused by the disc (ie, axial neck or low back, with or without somatic referred pain).
2. The suspected source of pain identified through other diagnostic imaging testing (eg, MRI, myelography, CT) needs to be in-

vestigated and confirmed.
3. New or different treatment will be instituted based on the results of the discography. At this time, there are few treatments that would be indicated by a positive discography result; therefore, judicious use of this procedure is indicated.

Contraindications to Disc Stimulation:
1. Spinal cancer consistent with the patient's pain complaint.
2. Systemic or local infection near the injection site.
3. Spinal cord, conus or cauda equina compression.
4. Pregnancy.
5. Patient unable to cooperate with the procedure and/or inability to assess patient response.

Procedural Requirements, Utilization and Restrictions
In the lumbar spine, manometry must be used to determine and record opening pressure, pressure at pain onset and peak pressure.
1. Intradiscal antibiotics are recommended to prevent infection.
2. The study should be performed under fluoroscopic or CT guidance.
3. Post-injection radiographic images (ie, AP and lateral radiographs) must be retained and made available upon request. Further post-injection imaging (CT or MRI) may be warranted.
4. Procedure must be performed by a licensed professional who has received appropriate training (eg, fellowship training) in the above techniques.
5. Sedation must be kept to a minimum to avoid interference with the patient's ability to accurately communicate and evaluate any provoked pain.

Provocation Discography:
Lumbar Spine
To maximize positive predictive value, minimize false positive tests and prevent harm (particularly regarding pressurization limits), Spine Intervention Society (SIS) and the Multi-society Pain Workgroup (MPW) consensus guidelines require:
1. Concordant pain response of ≥6/10 on a modified VAS 10 point scale.
2. Volume limit of 3 mL.
3. Pressurization of the disc to 15-20 psi above opening pressure, but no greater than 50 psi.
4. Adjacent disc(s) provide controls.
    a. For one control disc:
        i. Painless response.

    OR

        ii. Non-concordant pain that occurs at a pressure >15 psi over opening pressure.
    b. For two adjacent control discs:
        i. Painless response at both levels.

    OR

        ii. One painless disc AND one disc with non-concordant pain that occurs at a pressure >15 psi over opening pressure.

Cervical Spine
Since facet-mediated pain is more prevalent than discogenic pain in the cervical spine, facet-mediated pain should be ruled-out with medial branch blocks prior to performing discography in the cervical spine. A disc is considered positive only if stimulation of the target disc reproduces concordant pain with a 7/10 on a VAS modified 10 point scale or 70% of most severe pain the patient experiences and at least one adjacent disc that does not produce pain or produces non-concordant pain with a low volume injection.

Functional Anesthetic Discography:
Currently, there is not enough high-quality literature available to support the use of functional anesthetic discography.

Rationale

Lumbar Discography

Lumbar Discography is a tool utilized to assist in the diagnosis of chronic low back pain refractory to conservative modalities.
In Item 1, the rationale for coverage for lumbar discography is based on current practice patterns and known disc pain referral patterns.[19-20]

In Items 2 and 3, because of the known shortcomings and risks of discography, if a clear cause of the patient's pain is known based on imaging studies, or if performing this procedure will not change the treatment, then the need for discography is eliminated.[7-9, 11-14, 18, 21-24]

There has been a significant amount of literature published on complication rates for discography.[7] Complications can include disc injury, discitis, dural tears, bleeding, epidural abscess, chemical meningitis, allergic reaction to the dye, and injury to the nerve root.[18, 23] In the NASS statement of 1988, the rate of discitis was found to be 0.1-0.2%.[8-9, 18, 24]

The invasive studies show complication rates of 0.15% per disc and also from 0.5% to 13.1% per patient.[25-28] In one large meta-analysis, the rate of discitis was 0.15% and 0.44% among patients.[27] Thus, if the procedure is performed by a trained professional in accordance with established guidelines, the risk of complications can be greatly minimized.[29]

Cervical Discography

Cervical discography is intended to identify a painful cervical disc as well as identify internal derangements.[30] Siebenrock et al in 1994 found 75% of patients at one-year post cervical fusion diagnosed by discography had good to excellent results.[31] This increased to 86% at two-year follow up.[31] Other outcome studies have shown positive results.[31-33]

Zheng et al concluded that MRI can be used as a screening test in patients presenting with cervical discogenic pain, whereas discography can be used as an adjunct confirmatory test, avoiding fusion at unnecessary levels.[34] Also, discography was found to be helpful in differentiating between painful disc and asymptomatic discs in the older population.[35] However, Bogduk and Aprill found that due to the high prevalence of cervical zygapophysial joint pain, the false-positive rate of cervical discography was unacceptably high if zygapophysial joint pain had not first been excluded.[36] In the 56 patients studied, disc stimulation was clearly positive in only 11 (20%). It was false positive in 23 patients (41%) whose pain was relieved by zygapophysial joint blocks. These figures suggest a false-positive rate of 72% (23/32) and a positive predictive value of only 32% (11/34), unless zygapophysial joint pain is first excluded before undertaking cervical disc stimulation.

The greatest concern with cervical discography is the lack of a standardized grading system for what constitutes as a positive response.[30] In a systematic review by Onyewu et al, 41 manuscripts were reviewed.[37] As he noted in the review, there is a paucity of literature, which limits the evaluation of cervical discography. More high quality studies need to be developed in order to determine the utility of this procedure in the cervical spine. For a patient who has failed all conservative measures, the following recommendations can be made.[30]

1. Cervical discography is appropriate for patients who have failed 6 months of conservative measures for whom no imaging studies have provided an accurate diagnosis and when there is no evidence of infection, tumor, or cord compression.
2. The test is deemed positive only if stimulation of the target disc reproduces pain at 7/10 on a VAS modified 10 point scale or 70% of the most severe pain the patient experiences at low pressure levels and two adjacent discs do not produce any pain at all with low volume and low pressure injection.

Functional Anesthetic Discography Background

Anesthetic discography has been suggested as an adjunct or a stand-alone test to determine a painful disc and/or painful segments in patients with a previous fusion.[38-44] Bavtynski et al did a prospective review of 182 painful segments in 111 patients. The results showed that 74% of patients with leaking discs experienced near complete or complete pain relief after injection with intradiscal lidocaine. Although in contained discs, pain relief was limited.[45]

As a subset, Kimura et al injected segments with previous anterior interbody fusions.[46] These patients underwent revision surgery with long-term pain relief. This was also discussed in one case study.[47]

However, other studies have shown the contrary.[48-50] Derby et al found no difference between injection of a local anesthetic and con-

trast.[51] In another prospective clinical series, the outcomes were limited with no definite clinical indications. They do recommend further evaluation to determine the clinical efficiency of the test.[49]

Of greatest concern are the effects of the anesthetic agents in the intervertebral disc cells. Iwasaki et al studied the effects of analgesic injection on rabbit intervertebral discs.[51] There was no cell degeneration beyond the mechanical damage of pressurization of the disc. In contrast, other studies looking at the effects of anesthetic agents on bovine and human intervertebral cells showed cell death which could lead to further intervertebral degeneration. In a separate study, a steroid injection into the disc was compared with an anesthetic injection with no significant benefit.[52]

Although several case studies have shown the efficiency of further delineating the painful segment in both the nonoperated and the previously operated spine[46, 53-55], sufficient literature is not available to provide coverage recommendations for functional anesthetic discography. Most consist of case studies with little Level 2 evidence to support or to reject its use. Of concern is the effect of the anesthetic agents on the cell integrity of the intervertebral disc leading to further degeneration. Anesthetic discography does appear to be helpful to determine pseudarthrosis in a previously operated segment (especially previous interbody fusions). In this situation, further degeneration is not a concern. It may be used as an adjunct to provocative discography to determine surgical decision-making in some cases. However, the effects in the intervertebral disc cells should be considered when doing so.

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Additional Resources

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Level B.	$1,001 to $10,000	Level G.	$500,001 to $1M
Level C.	$10,001 to $25,000	Level H.	$1,000,001 to $2.5M
Level D.	$25,001 to $50,000	Level I.	greater than $2.5M
Level E.	$50,001 to $100,000		

NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. ***The coverage recommendations do not represent a "standard of care,"*** *nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient's needs as well as the doctor's professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.*

Financial Statement

These Coverage Recommendations were developed in their entirety by the North American Spine Society (NASS). All participating authors have disclosed potential conflicts of interest consistent with NASS' disclosure policy.

Author Disclosures

Baisden, Jamie L.: Nothing to Disclose.

Baisden, Jamie L.: Nothing to Disclose.

Bhowmick, Deb A.: Speaking and/or Teaching Arrangements: Medtronic Inc. (B).

Bono, Christopher M.: Royalties: Wolters Kluwer (A); Consulting: CRICO (C), United Health Care (B); Board of Directors: North American Spine Society (D); Other Office: JAAOS (B); Fellowship Support: OMEGA (D).

Bydon, Mohamad: Nothing to Disclose.

Cowan, R. Scott: Consulting: LDR (B); Research Support - Investigator Salary: LDR (B); Relationships Outside the One-Year Requirement: LDR (A).

Dazley, Justin M.: Nothing to Disclose.

DePalma, Michael J.: Consulting: Vertiflex, Inc (Financial, Hourly consultant); Trips/Travel: Medtronic (Financial, Paid directly to institution/employer); Board of Directors: International Spine Intervention Society (Financial, Paid directly to institution/employer), Virginia Spine Research Institute, Inc (Financial, Salaried position as President; Paid directly to institution/employer); Scientific Advisory Board: Medtronic; Halyard; Mesoblast (Financial, Paid hourly for participation in clinical advisory board meetings, Paid directly to institution/employer); Research Support - Investigator Salary: Relievant (B, Paid directly to institution/employer), SI Bone (B, Paid directly to institution/employer), Mesoblast, Inc (B, Paid directly to institution/employer), Vertiflex (B, Paid directly to institution/employer), Halyard (B, Paid directly to institution/employer), Discgenics (C, Paid directly to institution/employer), Samumed (B, Paid directly to institution/employer), Vivex (B, Paid directly to institution/employer); Research Support - Staff and/or Materials: Relievant (B, Paid directly to institution/employer), Mesoblast (B, Paid directly to institution/employer), SI Bone (B, Paid directly to institution/employer), Vertiflex (B, Paid directly to institution/employer); Other: AnGes Data Safety Monitoring Board (Financial, Hourly consulting fees, Paid directly to institution/employer); Relationships Outside the One-Year Requirement: AOI Medical (A), Stryker Interventional Spine (B), St. Jude Medical (03/2010, Consulting), Kyphon/Medtronic (B), Stryker Biotech (A), ATRM (A).

Dietze, Donald: Consulting: Medtronic (None), Osseus Fixation Devices (None) Joimax Spine (None), Precision Spine (B), NeXXT Spine (None).

Easa, John E.: Stock Ownership: Janus Biotherapeutics (1%, Paid directly to institution/employer).

Ghiselli, Gary: Royalties: New Era Orthopedics (B); Private Investments: DiFusion (9%).

Glaser, John A.: Relationships Outside the One-Year Requirement: SI Bone (dissolved 1/1/15, Grant).

Goldstein, Christina L.: Speaking and/or Teaching Arrangements: AOSpine North America (A); Trips/Travel: AOSpine North America (B), DePuy Synthes Spine (A); Other Office: AOSpine North America (Fellowship Committee), North American Spine Society (Coverage Committee), North American Spine Society (Section on Biologics and Basic Science); Grants: University of Missouri Coulter Translational Partnership (C, Paid directly to institution/employer).

Harrop, James S.: Consulting: Ethicon Spine (B, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: Medtronic (None); Scientific Advisory Board: Bioventus (B); Research Support - Investigator Salary: AONA Spine (B, Paid directly to institution/employer); Research Support - Staff and/or Materials: AO Spine (C, Paid directly to institution/employer); Grants: AO Spine (E, Paid directly to institution/employer); Fellowship Support: NREF (A, Paid directly to institution/employer); Other: Tejin (Data safety monitoring board).

Holt, Timothy A.: Speaking and/or Teaching Arrangements: SI Bone (E, Paid directly to institution/employer).

Horn, Scott I.: Speaking and/or Teaching Arrangements: North American Spine Society (Travel Expenses) AAPMR (Travel Expenses), SIS (Travel expenses); Board of Directors: Spine Intervention Society (Travel Expenses); Other Office: CPT Advisor for SIS (Travel Expenses.).

Hwang, Steven W.: Speaking and/or Teaching Arrangements: Zimmer-Biomet (B); Trips/Travel: NASS (A).

Kennedy, D.J.: Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel Expenses); Trips/Travel: AAPM&R (Travel Expenses), Spine Intervention Society (Travel Expenses); Board of Directors: AAPM&R (Board of Directors, Member at Large), Spine intervention Society (Board of Directors, Member at large).

Kreiner, Scott: Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel Expenses); Trips/Travel: MPW AUC on Vertebral Augmentation (B).

Krishnaney, Ajit A.: Speaking and/or Teaching Arrangements: Stryker (C).

Lebl, Darren R.: Private Investments: Woven Inc (<1%); Consulting: Nuvasive (B); Scientific Advisory Board: K2M MIS Advisory Team (B); Research Support - Staff and/or Materials: K2M (B, Research support, Paid directly to institution/employer).

Lapinsky, Anthony S.: Royalties: RTI Surgical (C, Royalties).

Matz, Paul G.: Nothing to Disclose.

Mayer, E. Kano A.: Stock Ownership: Infinite Orthopedics (1%,); Private Investments: Trabecular (16%); Speaking and/or Teaching Arrangements: North America Spine Society (B); Trips/Travel: American College of Surgeons (Travel Expenses), North American Spine Society (B).

O'Brien, David R.: Stock Ownership: Orthocarolina, Transformant health, Arrowlytics (1%); Private Investments: North American Spine Society (B); Speaking and/or Teaching Arrangements: SIS (Travel Expenses); Trips/Travel: SIS (Travel Expenses).

Patel, Alpesh A.: Royalties: Amedica (B); Stock Ownership: Amedica (<1%), Cytonics (<1), Nocimed (<1), Vital5 (<1%), Endoluxe (1%), Tissue Differentiation Intelligence (1%); Consulting: Amedica (None), Zimmer Biomet (B), Depuy Synthes (None), Nuvasive (None); Board of Directors: Cervical Spine Research Society (None), Lumbar Spine Research Society (None); Grants: Cervical Spine Research Society (B, Paid directly to institution/employer); Fellowship Support: AO Spine North America (E, Paid directly to institution/employer), Nuvasive (D, Paid directly to institution/employer), Globus (D, Paid directly to institution/employer).

Reiter, Mitchell F.: Private Investments: CreOsso (4%).

Reitman, Charles A.: Trips/Travel: NASS - BOD (Travel Expenses); Scientific Advisory Board: Clinical Orthopedics And Related Research - Deputy Editor (B).

Sanford, Timothy: Nothing to Disclose.

Schneider, Byron J.: Consulting: AIM Specialty (B), PDA (B); Speaking and/or Teaching Arrangements: NASS (Travel expenses Honorarium for speaking), SIS (A); Trips/Travel: AAPM&R (A); Scientific Advisory Board: Tennessee State Technical Advisory Committee Spine Episodes of Care (Nonfinancial, $0).

Seldomridge, Alex: Nothing to Disclose.

Sharan, Alok D.: Royalties: Jaypee Publishers (A); Stock Ownership: Medtel (1%), Revivo (1%); Consulting: Cartiva (B), McKinsey (B); Speaking and/or Teaching Arrangements: Globus (None); Trips/Travel: Globus (B); Board of Directors: Indo-American Spine Alliance (None); Scientific Advisory Board: Revivo (None); Other: Jaypee Brothers (A).

Smuck, Matthew: Stock Ownership: NuSpine (1%), Lumo Body Tech (1%), BlueJay Mobile-Health (1%); Private Investments: Vivametrica (15%); Trips/Travel: Spine Intervention Society, Board of Directors (B), North American Spine Society, Board of Directors (B); Board of Directors: Foundation for PM&R (None), Spine Intervention Society (None), North American Spine Society (None); Scientific Advisory Board: NuSpine (Stock options), Lumo Body Tech (Stock options), BlueJay Mobile-Health (Stock options); Other Office: Foundation for PM&R (None), Spine Intervention Society (None), North American Spine Society (None); Grants: ReWalk (E, Paid directly to institution/employer), Hyundai (E, Paid directly to institution/employer), Phillips (C, Paid directly to institution/employer), Relievant Medsystems (B); Other: Expert witness - State Farm (F).

Summers, Jeffrey T.: Stock Ownership: NEVRO (<1%).

Tontz, William L.: Device or Biologic Distributorship (Physician-Owned Distributorship): Aliphatic (A, Paid directly to institution/employer); Stock Ownership: Phygen (<1%, none, Paid directly to institution/employer); Consulting: Medtronic (B); Speaking and/or Teaching Arrangements: SpineArt (A); Trips/Travel: Stryker (B); Scientific Advisory Board: Medtronic (Consulting, Paid directly to institution/employer).

Truumees, Eeric: Trips/Travel: AAOS (B); Board of Directors: Seton Family of Doctors (Salary); Other Office: AAOS Communications Cabinet (E); Research Support - Staff and/or Materials: Relievant (B, Paid directly to institution/employer), Medtronic (A, Paid directly to institution/employer), Vertex Pharma (A, Paid directly to institution/employer), Dova Pharmaceuticals (A, Paid directly to institution/employer), Pfizer (B, Paid directly to institution/employer), Stryker Spine (B, Paid directly to institution/employer).

Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.